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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/855,945	05/14/2001	Clifton A. Alferness	1931-2	1454

996 7590 06/05/2003
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EXAMINER

CHATTOPADHYAY, URMI

ART UNIT	PAPER NUMBER
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3738

DATE MAILED: 06/05/2003

13

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/855,945

Applicant(s)

ALFERNES ET AL.

Examiner

Urmi Chattopadhyay

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 March 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4-15,41,42 and 44-57 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,4-15,41,42 and 44-57 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 14 May 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

1. The amendment filed 3/7/03 has been entered as Paper No. 11. Claims 3, 16-40 and 43 have been canceled. The prior art rejections set forth in the office action mailed 12/20/02 has been withdrawn. However, new art rejections are set forth below rendering this office action as non-final.

Election/Restrictions

2. Applicant's election without traverse of the species of Figure 10 in Paper No. 11 is acknowledged. The claims being considered for further examination on the merits are 1, 2, 4-15, 41, 42 and 44-57.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 1, 4-7, 9-11, 15, 41, 44-47, 49-51 and 55-57 are rejected under 35 U.S.C. 102(e) as being anticipated by Langberg et al. (USPN 6,402,781).

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Langberg et al. discloses an assembly for effecting the condition of a mitral valve annulus and a mitral valve annulus constricting or therapy device with all the elements of claims 1, 41, 56 and 57. See column 10, lines 40-44 for a guide wire configured to be fed into the coronary sinus of the heart and a mitral valve annulus device (66) configured to be slidably received on the guide wire and advanced into the coronary sinus of the heart on the guide wire and that reshapes the mitral valve annulus when in the coronary sinus of the heart (see abstract). The guide wire lumen that extends from one end of the device to an opposing end forms a guide wire engaging structure at at least one of the ends thereof. For claims 56 and 57, see Figure 2 for device having an arched configuration and being a generally C-shaped member.

Claims 4-7 and 44-47, see column 10, lines 40-44. The lumen, which is inherently cylindrical in shape, defines bores at each of the ends of the device, which are dimensioned to permit the guide wire to pass therethrough, and a channel extending between and aligned with the bores.

Claims 9, 10, 49 and 50, see column 8, lines 31-43 for device (66) being a metal support, and metal is inherently visible under X-ray fluoroscopy.

Claims 11 and 51, see Figure 4 for an elongated introducer (86) having a lumen (88), thereby making it capable of being slidably received on the guide wire proximal to the device.

Claims 15 and 55, see Figure 3 and column 10, lines 54-60 and column 11, lines 18-20 for guide tube (74) having an inner lumen (84).

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5. Claims 1, 2, 4-11, 13, 14, 41, 42, 44-51, 53, 54, 56 and 57 are rejected under 35

U.S.C. 102(e) as being anticipated by Taylor et al. (USPAP 2002/1083835).

Taylor et al. discloses an assembly for effecting the condition of a mitral valve annulus and a mitral valve annulus constricting or therapy device with all the elements of claims 1, 41, 56 and 57. See Figures 12 and 13 for a guide wire (103) configured to be fed into the coronary sinus of the heart and a mitral valve annulus device (184) configured to be slidably received on the guide wire (103) and advanced into the coronary sinus of the heart on the guide wire (103) and that reshapes the mitral valve annulus when in the coronary sinus of the heart (see abstract). The guide wire lumen (193) that extends from one end of the device to an opposing end forms a guide wire engaging structure at at least one of the ends thereof. See [0092]. For claims 56 and 57, see [0099] for device having an arched configuration and being a generally C-shaped member.

Claims 2 and 42, see [0068] for coiled guide wire.

Claims 4-7 and 44-47, see Figures 12 and 13 and [0092]. The lumen (193), which is inherently cylindrical in shape, defines bores at each of the ends of the device, which are dimensioned to permit the guide wire (103) to pass therethrough, and a channel extending between and aligned with the bores.

Claims 8-10 and 48-50, see [0064] and [0097]. Because fluoroscopy is used to visualize the implantation process, it is inherent that the guide wire and device are made of a material that would be visible by this technique.

Claim 11 and 51, see Figures 12 and 13 and [0093] for elongated introducer (187) configured to be slidably received on the guide wire (103) proximal the device (184).

Claims 13, 14, 53 and 54, see [0098] for locking mechanism to releasable lock the proximal end (190) of the device to the distal end of the introducer (187).

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 2, 8, 12, 42, 48 and 52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Langberg et al. in view of de Toledo et al. (USPN 4,830,023 as cited in last office action).

Langberg et al. discloses an assembly for effecting the condition of a mitral valve annulus with all the elements of claims 1 and 41, but is silent to the guide wire being formed of a material visible under X-ray fluoroscopy, and the guide wire and introducer being an elongated coil, as required by claims 8, 48 and 2, 12, 42, 52, respectively. de Toledo et al. teaches a metal guide wire (claims 8 and 48) being an elongate coil in order for it to have greater flexibility (claims 2, 12, 42 and 52). See abstract. Because both the guide wire and introducer of Langberg et al. require flexibility to travel through the venous system into to the coronary sinus, it would have been obvious to one of ordinary skill in the art at the time of applicant's invention to look to the teachings of de Toledo et al. to modify the guide wire so that it is made of metal, and therefore by nature visible under X-ray fluoroscopy, and the guide wire and introducer of Langberg et al. such that they are elongated coils in order for them to have greater flexibility for the travel.

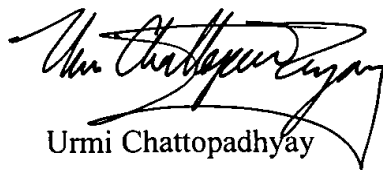
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8. Claims 12 and 52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Taylor et al. in view of de Toledo et al.

Taylor et al. discloses an assembly for effecting the condition of a mitral valve annulus with all the elements of claims 1 and 41, but is silent to introducer being an elongated coil, as required by claims 12 and 52. de Toledo et al. teaches a guide wire being an elongate coil in order for it to have greater flexibility. See abstract. Because the introducer of Taylor et al. requires flexibility to travel through the venous system into to the coronary sinus, it would have been obvious to one of ordinary skill in the art at the time of applicant's invention to look to the teachings of de Toledo et al. to modify the introducer of Taylor et al. such that it is an elongated coil in order for it to have greater flexibility for the travel.

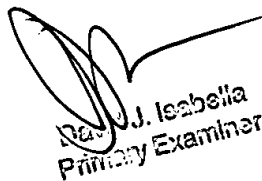
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ms. Urmi Chattopadhyay whose telephone number is (703) 308-8510 and whose work schedule is Monday-Friday, 9:00am – 6:30pm with every other Friday off. The examiner's supervisor, Corrine McDermott, may be reached at (703) 308-2111. The group receptionist may be reached at (703) 308-0858.

Should the applicant wish to send a fax for official entry into the file wrapper the Group fax number is (703) 305-3590. Should applicant wish to send a fax for discussion purposes only, the art unit fax number is (703) 308-2708.



Urmi Chattopadhyay

Art Unit 3738



J. Isabella
Primary Examiner

uc

May 30, 2003